

### **REMARKS**

Claims 42-48, 52-57, and 60 are pending in the application with claims 42, 60, and 61 being the independent claims. Claim 42 is amended. Claim 61 is newly added. Applicants request reconsideration in view of the following remarks.

#### **Drawings**

The Office Action indicates the drawings must show the elastic material in claims 42 and 60. Claim 42 recites, for example, an “elastic material being disposed through both the first and second openings in a manner that dynamically secures the first and second components together and elastically flexes in a manner that permits relative movement between the first and second components” and “a connector covering the first joint element and the second joint element, wherein the connector comprises the elastic material.” Emphasis added

The specification states:

The joint 410 comprises an opening 412, which may contain any biocompatible elastic material, such as rubber, silicon or shape memory alloys, to facilitate motions of the posterior device 400. The opening 412 may be coupled to the opening 404, so that an elastic material may flow through both openings 404 and 412 to facilitate the functions of the posterior device 400.

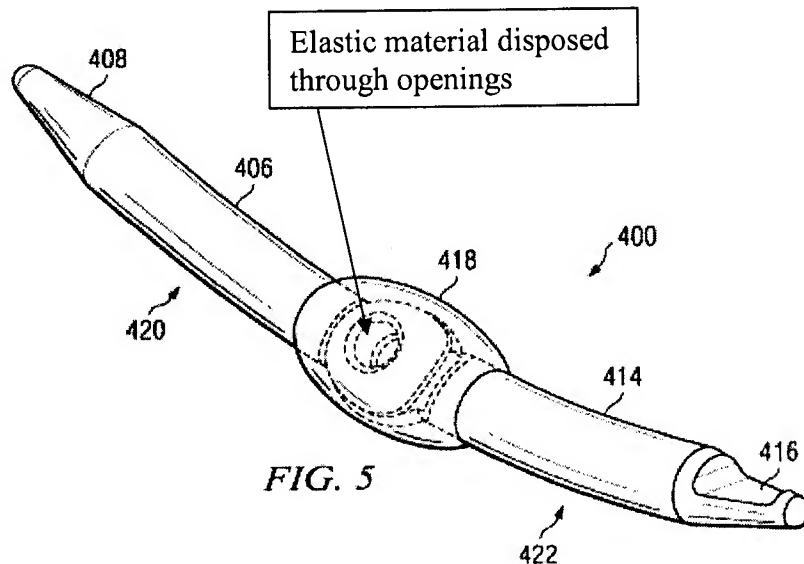
Para. [0046]. It also states:

The first and second components 420 and 422 may be coupled together by any conventional means, such as being molded or screwed together through their respective joints 402 and 410, to form a unit.

Para. [0047]. One example of one exemplary embodiment of the disclosed device is shown in Fig. 5 of the application, where a connector comprises the elastic material and the elastic material is disposed through first and second openings.

For reference, Fig. 5 is reproduced below with a legend identifying one example of a connector 418 comprising the elastic material and the elastic material being in openings. This example appears to disclose the exemplary described embodiment where the first and second

components are molded together and where the elastic material has flowed through both openings.



Because the elastic member is already shown in the drawing as a part of the connector 418, Applicants request that the Examiner withdraw the objection.

Compliance with 35 U.S.C. §112

The Office Action rejected claims 42-48 under the first and second paragraphs of Section 112 for reciting “rigid portions” and for lacking antecedent basis for “rigid portions.” Applicants have amended claim 42 to recite the first and second components instead of the rigid portions. Accordingly, Applicants respectfully request that the Examiner withdraw the rejections.

The Office Action rejected claims 42-48 under the second paragraph of Section 112 indicating that the it is “unclear if applicant is claiming the individual parts which must be flexible relative to the vertebrae, or if applicant is trying to claim that the entire device, shown in Fig. 4, is itself a ‘flexible member.’” Office Action, p.3-4. Claim 42 may be interpreted to be either of the examples indicated by the examiner. The flexible member as a whole is flexible at

least by virtue of the flexible elastic material and flexible connector. On the other hand, the components 420, 422 (see Fig. above) may comprise any biocompatible material including, for example, stainless steel (likely a rigid or non-flexible member) as well as shape memory alloys, polymers, and others (that may be relatively flexible materials). See Application, para. [0048]. Accordingly, Applicants submit that the claim particularly points out and distinctly claims the recited subject matter. Applicants respectfully request that the Examiner withdraw the rejection.

Compliance with 35 U.S.C. §103

The Office Action indicated that claims 42-48, 52-57, and 60 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,238,396 to Lombardo in view of 2003/0220643 to Ferree. Applicants traverse the rejection.

Claim 42 is directed to a surgical implant for replacing functions of a facet joint between adjacent vertebrae. It includes first and second biocompatible attachment devices for attaching to pedicles and:

- a flexible member attached to the first and second biocompatible attachment devices configured in a manner to allow motion at the facet joint;

- wherein the first and second biocompatible attachment devices are positioned, and the flexible member is adapted, so that the surgical implant applies a distracting force between the superior and inferior vertebrae sufficient for maintaining the first and second pedicles at a spaced-apart distance,

- wherein the flexible member includes:

- a first component comprising: an elongated body and a first joint element having a first opening;

- a second component comprising: an elongated body and a second joint element having a second opening wherein the second joint element is coupled with the first joint element;

- an elastic material disposed through both the first and second openings in a manner that dynamically secures the first and second components together and elastically flexes in a manner that permits relative movement between the first and second components; and

a connector covering the first joint element and the second joint element, wherein the connector comprises the elastic material.

Emphasis added.

The Office Action fails to identify any portion of any applied reference that suggests a “flexible member is adapted, so that the surgical implant applies a distracting force between the superior and inferior vertebrae sufficient for maintaining the first and second pedicles at a spaced-apart distance,” as recited in claim 42. The device Lombardo is a cross-connector that extends in a lateral direction across a vertebral posterior region. It does not provide a distracting force between superior and inferior vertebrae as required by claim 42.

Ferree does not help. Ferree is relied on for a teaching of a protective cover. A protective cover on a cross-connector does not provide a distracting force between superior and inferior vertebrae as claimed because the cross-connector is typically used to fix the vertebrae in a position relative to each other. Further, the other teachings in Ferree would not help because placing springs as in Ferree in a cross-connector as in Lombardo would still not provide any distracting force between superior and inferior vertebrae.

In addition, the combination of references fails to suggest “an elastic material that flexes to impart flexibility to the flexible member, the elastic material being disposed through both the first and second openings in a manner that dynamically secures the first and second components together and elastically flexes in a manner that permits relative movement between the first and second components,” as recited in claim 42.

The Office Action relies upon Lombardo for a teaching of an elastic material disposed through both a first and second opening in first and second components. Although Lombardo discloses what appears to be a traditional screw, the Office Action states, “it would have been obvious to one having ordinary skill in the art at the time of the invention” to make the screw in Lombardo elastic because it is “within the general skill of a worker in the art to select a known

material on the basis of its suitability of the intended use as a matter of obvious design choice.”  
Figs. 3 and 6 from Lombardo are reproduced below.

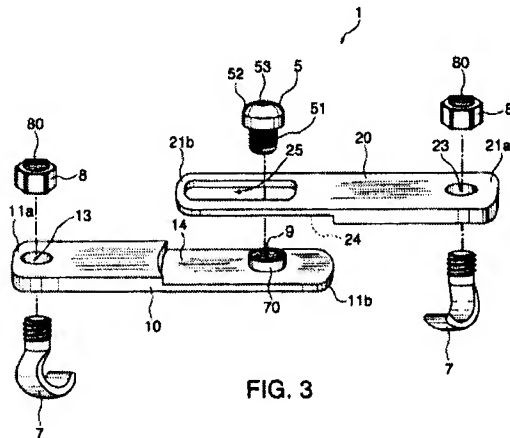


FIG. 3

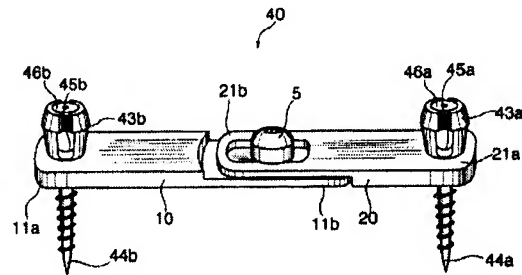


FIG. 6

Lombardo discloses a cross-connecting apparatus having a screw as a “tightening device 5.” According to Lombardo, “[t]he tightening device 5 is positioned through the elongated aperture 25 of the second element 20 and within the central bore 9 of the first element 10 to secure the second element 20 onto the first element 10.” Lombardo, col.9 ll.38-41. But the screw in Lombardo is not “disposed ... in a manner that dynamically secures the first and second components together and elastically flexes in a manner that permits relative movement between the first and second components.” Instead, the screw 5 in Lombardo permits pivoting of the device prior to be tightened down. But a screw that permits pivoting is not equivalent to an elastic member that “elastically flexes in a manner that permits relative movement between the first and second components” because the screw does not flex. Thus it cannot impart the same type of biasing force provided by an elastic member. Furthermore, an elastic member that elastically flexes in a manner that permits relative movement would be undesirable in a cross-connector because the cross-connector is intended to rigidly align two rods. A loose cross-connector might result in a loose rod. Thus, a cross-connector that elastically flexes would render the cross-connector unsuitable for its intended purpose of stiffening or strengthening the spine.

Accordingly, Applicants respectfully submit that the Office Action fails to establish a prima facie rejection and that claim 42 should be allowed as was indicated in the prior Office Action.

Claim 60

Claim 60 is directed to a prosthetic device for replacing functions of a facet joint between adjacent vertebrae. It includes

one or more flexible posterior devices configured to replace main functions of the facet joint, having a first biocompatible attachment device configured to attach to a first transverse process, and a second biocompatible attachment device configured to attach to a second transverse process, and wherein the one or more flexible posterior devices includes a joint component positioned between the first and second biocompatible attachment devices, wherein the one or more flexible posterior devices comprises:

- a first elongated body; and
- a second elongated body,

wherein the joint component includes:

- a first element associated with the first elongated body, the first element having a first opening, and
- a second element associated with the second elongated body, the second element having a second opening, wherein the second element is coupled with the first element by an elastic material disposed in both the first and second openings; and
- a connector covering the first element and the second element wherein the connector comprises the elastic material.

However, Applicants submit that the combination of references fails to include “one or more flexible posterior devices configured to replace main functions of the facet joint, having a first biocompatible attachment device configured to attach to a first transverse process, and a second biocompatible attachment device configured to attach to a second transverse process.” Instead, the Lombardo device is configured to attach to spinal rods or to pedicles. Ferree appears to disclose a device for connection to pedicles. Neither discloses “a first biocompatible attachment device configured to attach to a first transverse process, and a second biocompatible

attachment device configured to attach to a second transverse process,” as recited in claim 60. Accordingly, the combination fails to teach or suggest all the features of claim 60.

Accordingly, Applicants respectfully submit that the Office Action fails to establish a prima facie rejection and that claim 60 should be allowed as was indicated in the prior Office Action.

#### New Claim

Applicants add new claim 61. Claim 61 is like claim 42 in many respects but includes additional features. Those features are underlined in the reproduced claim below.

A surgical implant for replacing functions of a facet joint between adjacent vertebrae, the surgical implant comprising:  
a first biocompatible attachment device for attaching to a first pedicle of a superior vertebrae;  
a second biocompatible attachment device for attaching to a second pedicle of an inferior vertebrae; and  
a flexible member attached to the first and second biocompatible attachment devices configured in a manner to allow motion at the facet joint;  
wherein the first and second biocompatible attachment devices are positioned, and the flexible member is adapted, so that the surgical implant applies a biasing distracting force between the superior and inferior vertebrae sufficient for maintaining the first and second pedicles at a spaced-apart distance,  
wherein the flexible member includes:  
a first component comprising: an elongated body and a first joint element having a first opening;  
a second component comprising: an elongated body and a second joint element having a second opening wherein the second joint element is coupled with the first joint element;  
an elastic material that flexes to impart flexibility to the flexible member, the elastic material being disposed through both the first and second openings in a manner that dynamically secures the first and second components together and elastically flexes in a manner that permits relative movement between the first and second components and the superior and inferior vertebrae; and

a connector covering the first joint element and the second joint element, wherein the connector comprises the elastic material.

Applicants submit that claim 1 should be allowable for the reasons discussed above and because it recites additional patentable subject matter.

#### Dependent Claims

The dependent claims add additional features to respective independent claims and also are believed to be distinct from the art of record, for example for the same reasons discussed above with respect to their respective independent claims. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of these claims.



Conclusion

For at least the reasons set forth above, Applicants respectfully request that the Examiner reconsider and issue a formal notice of allowance. If the Examiner determines that a telephone discussion with the undersigned would further prosecution of the application, the Examiner is invited to telephone the undersigned at 972-739-6969.

The Office Action and other prior Office Actions contain characterizations of the claims and the related art to which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

Please grant any extension of time required to enter this response and charge any additional fees required by this paper to our Deposit Account No. 08-1394.


Respectfully submitted,



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I hereby certify that this correspondence is being filed with the U.S. Patent and Trademark Office via EFS-Web on October 16, 2008.
 Diane Sutton